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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,588	12/03/2004	Eishun Tsuchida	0020-5327PUS1	9917

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EXAMINER

AUDET, MAURY A

ART UNIT PAPER NUMBER

1654

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/516,588

Applicant(s)

TSUCHIDA ET AL.

Examiner

Maury Audet

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 5-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 03/05, 12/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

The present application has been transferred from former Examiner Shirali to the present Examiner. New claims 5-15 have been added and are examined on the merits. Claims 2 and 4 have been cancelled. The present action is being sent as a 2nd Action Non-Final, to clarify the previous 103 rejection (both references being Applicant's earlier works) as well as put of record other rejections not originally of writing. The pending claims are herein examined on the merits, but only as drawn to the elected species, as described in the previous action.

Claim Rejections - 35 USC § 112 1st Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, and 5-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant application, applicants claim an oxygen infusion comprising an albumin clathrate compound including a porphyrin metal complex; wherein, among other loci:

1. R1 is any one or more substituents; and
2. R4 is any group that does not inhibit coordination of said basic axial ligand [R2, formula A] to a central transition metal ion M.

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The MPEP clearly states that the purpose of the written description is to ensure that the inventor had possession of invention as of the filing date of the application, of the subject matter later claimed by him. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997). The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the application. These include, "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed invention is sufficient" MPEP 2163.

Regarding R1, claim 3 and new claims 5-6 describe that "the any one or more substituents" may be: C1-C19 chain hydrocarbon group; methyl; C1-C18 alkyl amide; C1-C18 alkanoyloxy; or C1-C18 alkoxy. Regarding R4, claim 3 describes that "the any group that does not inhibit coordination of said basic axial ligand (R2, formula A) to a central transition metal ion M" may be H, methyl, ethyl, or propyl. No other description for what either R1 or R4 may be was found in the specification.

As to R1, the literature indicates that a "substituent" is "*any* atom, group, or radical substituted for another" (<http://cancerweb.ncl.ac.uk/cgi-bin/omd?query=substituent>; March 1

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1998). Neither the prior art nor Applicant has not provided a description, other than those expressly claimed options discussed above, for what such “substituents” are capable of binding/enabling the albumin clathrate to be an oxygen infusion compound, other than those expressly defined/claimed. As to R4, no literature could be found on what can or cannot inhibit coordination of a basic axial ligand of formula A; therefore, absent any description to clearly define what such “substituents” are capable of binding/enabling the albumin clathrate to be an oxygen infusion compound, the prior art and present specification lack description, other than those atoms/groups described, for what may be attached at the R4 loci.

Thus, the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Therefore, the claims as recited lacks written description.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3 and 5-15 rejected under 35 U.S.C. 103(a) as being obvious over Tsuchida et al. I (Bioconjugate Chem., 1999, 10, 797-802)., and Tsuchida et al. II (Bioconjugate Chem., 2000, 11, 46-50). [Applicant's earlier publications].

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Tsuchida et al. I teach that substituted amido phenylporphinatoiron(II)s (FePs) are incorporated in hydrophobic cavities of recombinant human serum albumin (rHSA), providing a synthetic O₂ carrier hemoprotein under physiological conditions. (col.3, line 65). However, Tsuchida et.al. I does not teach the finding of cyclic amido phenylporphinatoiron (II).

Tsuchida et al. II teach that amidophenylporphinatoiron (II) analogs which are structurally very similar to the present substituted porphyrins in combination with albumin show a good activity in the anesthetized rats (page 47, results and discussion).

It would be been obvious to one of ordinary skill in the art at the time of the invention to make the substituted cyclic 1-methyl cyclohexanyl amido phenylporphinatoiron (II) in Tsuchida et al. I, because Tsuchida et al. II advantageously teach minor structural changes between this compound and the compounds made by Tsuchida I which would have been merely routine structural optimization by one of ordinary skill in the art to apply the substitutions of represented by the porphyrin of Tsuchida II; **because it binds oxygen better**. One of ordinary skill in the art would have readily ascertained that this would be an the result (rather than being unexpected).

Tsuchida et. al. I also showed that human serum albumin (HSA) incorporating synthetic hemes (FeP)s is an artificial hematoprotein (HSA-FeP) which is able to reversibly bind and release dioxygen under physiological conditions. The physiological response to exchange transfusion with HSA and (FeP)s into the rats was also taught. The reference also determined the half-life of deoxygenated HSA-FeP.

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It would be been obvious to one of ordinary skill in the art at the time of the invention to modify the compound of Formula I wherein R contains a methyl cyclohexanol substitution in Tsuchida et al. I because Tsuchida et al. I advantageously teach a nearly identical compound and one of ordinary skill in the art would have been motivated to make this substitution in Tsuchida et al. I alone (or in view of Tsuchida et al. II) in order to modify the phenylporphinatoiron (II) and use albumin clathrate as a dispersion.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

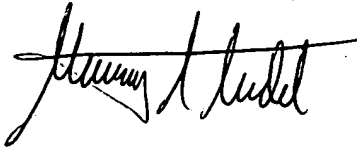
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 10/28/2006

MAURY AUDET
PATENT EXAMINER

A handwritten signature in black ink, appearing to read 'Maury Audet', written over a horizontal line.